**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327** |
| **THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

# MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this brief in support of their motion to exclude certain general opinions of Daniel Elliott, M.D., as it relates to the cases set forth in Exhibit A to Defendants' accompanying motion.

## INTRODUCTION

Dr. Elliott is a pelvic surgeon and urogynecologist in Minnesota with experience in the surgical treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as the removal of sling systems. Ex. B, curriculum vitae. Dr. Elliott intends to provide general opinions about TVT, TVT-O, and TVT Secur (collectively "the TVT Devices"), used to treat SUI, as well as Prolift, which is used to treat POP. Ex. C-F, Expert Reports.[1] As set forth below, the Court should preclude Dr. Elliott from testifying about matters that are beyond his expertise, that are unreliable, that are irrelevant, and/or that are otherwise improper.

## LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

[1] Because most of Dr. Elliott's opinions about the TVT Devices are the same, citations in this brief are generally limited to one of those reports.

## I. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI and POP.

Although he has never implanted a TVT Device, Dr. Elliott acknowledges that synthetic slings, such as TVT, are the most commonly used surgical treatment for SUI, that TVT is the most studied SUI surgical device, and that TVT is effective to treat SUI. Ex. G, 9/26/15 Dep. 116:12-117:4, 78:4-10, 89:12-90:1, 96:13-21, 99:21-100:9. Nevertheless, Dr. Elliott generally takes the position that the Prolene mesh in TVT Devices is unsafe and that autologous slings and Burch colposuspension (which he has not performed since performing only 2 Burch procedures during his residency) are safer alternative procedures. *Id.* at 28:14-18; Ex. C, TVT Report at 8-9. He also suggests that traditional surgical approaches, such as sacrocolpopexy and colporrhaphy, are a safer alternative to Prolift. (Ex. F, Prolift Report at 6-7, 56).

Any alleged comparative benefits of traditional surgical approaches to treat SUI or POP are not even relevant to Plaintiffs' design defect claims, because they are not medical devices. As noted in *Hines v. Wyeth*, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011):

> [A]n "alternative design must not be an altogether essentially different product." *Torkie*, 739 F.Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Id.; see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03–664, 2006 WL 1148506, *3 (W.D.Wash. Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design").

*See also Caterpillar, Inc.*, 911 S.W.2d at 385 (finding that the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable mind could conclude that traditional surgical approaches are *products*.

The notion that traditional surgical procedures are safer alternatives to Ethicon's devices is premised on the assumption that all mesh products are unsafe. Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the TVT device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (surgical alternative to pedicle screw could not be considered). As noted in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. 2013), "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim. In reality, Plaintiffs takes issue with the choice of their physicians in recommending a medical device (ie. TVT) rather than a non-medical device (ie. autologous slings).

Notably, Dr. Elliott fully agrees. Dr. Elliott has acknowledged that autologous slings and the Burch procedure are not medical devices. Ex. G, 9/26/15 Dep. 23:18-20, 25:3-5, 28:22-24. According to Dr. Elliott: "[W]hen we're talking about safety and complications, it's comparing *apples and oranges* because there is no medical device placed in those patients that's permanent. . . . Therefore, the bar is changed for the pubovaginal and Burch . . . . So really you *can't compare TVT mesh, or any mesh for that matter*, and the Burch or autologous fascia for that matter." *Id.* at 74:2-4, 93:18-21, 103:21-22 (emphasis added); *see also id.* at 73:23-24. Having acknowledged that it is inappropriate to compare Ethicon's devices with non-mesh procedures, Dr. Elliott should not be allowed to do otherwise by presenting any such comparison at trial.[2]

[2] Alternatively, this argument applies to the following Plaintiffs in which applicable state law requires a plaintiff to prove the availability of a feasible, safer alternative product: Amsden, Cole, Nix, Quijano & Wilson (Tex.--*Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256, 258 (Tex. 1999); Bennett, Clayton, Loustaunau, Morrow, Shively, Springer & Taylor (La.--La. Rev. Stat. § 9:2800.56; *Reeves v. AcroMed Corp*, 44 F.3d 300, 308 (5th Cir. 1995)); Boggs & Guinn (Ohio--OHIO REV. CODE § 2307.75(F)); Carpenter & Gray-Wheeler (Miss.--Miss. Code Ann. § 11-1-63(f)(ii); *Williams v. Bennett*, 921 So. 2d 1269, 1275 (Miss. 2006)); Dimock (Utah--*English v. Suzuki Motor Co*., 1997 U.S. App. LEXIS 19865, at *11 (10th Cir. 1997)); Kaiser (Ind.-- *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015); *Whitted v. Gen. Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir.1995); *Simmons v. Philips Elecs. N. Am. Corp.*, 2015 WL 1418772, at *10 (N.D. Ind. Mar. 27, 2015)); Long & Shepherd (Ky.--*Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 1991)); Lozano (Wis.--Wis. Stat. Ann. § 895.047(1)(a)); and Phelps (Md.-- *Nissan Motor Co. Ltd. v. Nave*, 740 A.2d 102, 118 (Md. Ct. Spec. App. 1999)).

**II. Alternatively, the Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI, because his opinions are unreliable.**

Dr. Elliott also should not be allowed to suggest that TVT Devices are more dangerous than non-synthetic mesh sling procedure, because any such opinions are unreliable and unhelpful. Asked why his expert report did not set forth any opinion about TVT complication rates, Dr. Elliott responded that it was "[b]ecause *we don't know* the true complication rate." Ex. G, 9/26/15 Dep. 196:7-14; *see also id.* at 110:13-17 (emphasis added). For this reason alone, the Court should exclude Dr. Elliott's opinions. Because Dr. Elliott admittedly does not feel qualified to testify about complication rates, he is not competent to opine that TVT Devices pose a higher risk of complications than non-mesh procedures.

Dr. Elliott's opinions should also be excluded because, rather than relying on medical studies and other sound scientific methodology in support of his opinions as required by *Daubert,* Dr. Elliott improperly relies on a perceived *lack of data* as a basis for his opinions. According to Dr. Elliott, "[t]he data overall with all sling products is very poor," including studies relating to autologous slings, "[a]nd that's why we're in the situation we're in now." *Id.* at 63:11-14, 75:17-76:21; 79:13-14. Dr. Elliott stated that he disagrees with the American Urological Association's ("AUA's") conclusion that synthetic polypropylene mesh has minimal morbidity compared to alternatives, but the basis for his disagreement simply is his belief that "there have been very few randomized control trials, none which are long-term, comparing head-to-head autologous pubovaginal slings versus TVT." *Id.* at 118:19-25; *see also id.* at 123:19-24; 187:21-188:1.

Aside from the fact that Dr. Elliott has a misperception about TVT Device literature, Dr. Elliott improperly infers that this perceived lack of studies demonstrates that the AUA is wrong

and that TVT is less safe than alternative surgical approaches. The essence of Dr. Elliott's opinions is that: (a) he is not really sure whether or not TVT Devices are safer than alternative procedures; (b) Ethicon should have conducted additional testing before marketing the devices; and (c) because Ethicon did not do so, he will assume that the TVT Devices are not as safe. This approach is far from trustworthy scientific methodology.

When asked about mesh-related pain, Dr. Elliott conceded: "The true incidence, unfortunately, is not known." Ex. G, 9/26/15 Dep. 261:1-5. He further testified:

> Q. Now, I believe you said that you believe that the long-term dyspareunia rates with the TVT were higher than pubovaginal, did you say, and the Burch?
>
> A. I don't recall if I mentioned the Burch in there. What I mentioned was the pubovaginal and the Burch have traditionally been a very common procedure done up until the mid-'90s and into probably early 2000's. And in my practice, I have never seen a woman come in with severe pain, life altering pain from either of those aforementioned procedures. But I see it commonly, weekly with the meshes, including the TVT.
>
> Q. You can't point to any comparative trials that show a statistically significantly higher rate of dyspareunia for the TVT retropubic device compared to either the Burch or the pubovaginal sling; correct?
>
> A. Those studies, as you've mentioned, *have not been done*.
>
> Q. And actually, the one paper you pointed me to earlier about the Burch had the 4 percent rate of dyspareunia with that procedure long-term; correct?
>
> A. It wasn't 4 percent. It was 3.9 percent.[3] . . .
>
> Q. Okay. And you can't point to any studies on TVT that show a rate higher than 3.9 percent at that length of follow-up for dyspareunia; can you?
>
> MR. CARTMELL: Object to the form.
>
> A. *Because that study has not been done*. As I mentioned, no studies focused specifically on output -- end point of dyspareunia have been done.

[3] Dr. Elliott refused to state whether he felt that 3.9% was acceptable. Ex. G, 9/26/15 Dep. 67:21-68:23. This same Burch study upon which Dr. Elliott relied showed an alarming 22% rate of urgency at long term follow up, demonstrating that the procedure is much less efficacious than TVT. *Id.* at 67:4-6; Ex. S.

*Id.* at 327:13-329:2 (emphasis added).

In fact, such studies have been done, and Dr. Elliott has chosen to ignore them. For instance, Heinonen and others performed a 10-year TVT study reporting zero cases of dyspareunia at 10 years follow-up, thus demonstrating that Dr. Elliott's understanding is flat wrong. Ex. H. Dr. Elliott could not recall whether he had reviewed that study. Ex. G, 9/26/15 Dep. at 329:11-21. Nor could Dr. Elliott reconcile his testimony with the AUA guideline and Society of Gynecological Surgeons' meta-analysis and systematic review, both of which reported higher rates of dyspareunia, pain, and sexual dysfunction with the autologous sling and Burch procedure as compared to mid-urethral mesh devices. *Id.* at 331:20-332:3; Ex. I & J. Even Dr. Elliott's own employer, the Mayo Clinic, advertises that "[u]sing surgical mesh is a safe and effective way to treat stress urinary incontinence." Ex. T.

Dr. Elliott has also arbitrarily discounted literature that he, himself, cites in his report. For instance, when asked about a Cochrane review cited in his own report, (Ex. U; Ex.C, TVT Report at 37 n. 98), Dr. Elliott testified as follow:

> Q. BY MR. SNELL: And this Cochrane Review you cite to in your report does say that "The reported occurrence of problems with sexual intercourse including pain was low" [concerning mesh devices]; correct?
>
> A. That's what they state, yes.
>
> Q. And you didn't acknowledge that point in your report; did you?
>
> A. I talk about dyspareunia in there.
>
> Q. Did you acknowledge that the Cochrane Review that you cite to states that problems with sexual intercourse, including pain, were low in your report?
>
> A. I don't recall using those specific words, no.
>
> Q. Why not?

> A. Because, again, this is a meta-analysis of poor quality or moderate quality studies that do not focus on dyspareunia. And specifically they're short-term studies. It does not tell -- also, these are in the hands of experts, high-volume surgeons. Does not tell us the rate of the true average surgeon out there, which is known to be much higher.

Ex. G, 9/26/15 Dep. 111:3-25. In fact, the authors of that Cochrane review upon which Dr. Elliott supposedly relied concluded: "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI." Ex. 4, to 9/26/15 Dep. (Ex.G), at 3.

In *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *8 (S.D. W. Va. Apr. 24, 2015), this Court noted that "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." (Citations omitted). Here, Dr. Elliott has achieved the conclusion that he wants to achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers. In the same manner, he has arbitrarily discounted other studies that do not comport with the opinions he would like to offer in this case. Because Dr. Elliott's failure to account for this literature is not based on any sound scientific principles, his opinions are unreliable and should be excluded.

Finally, the Court should find that Dr. Elliott's personal experiences—unsupported by any trustworthy scientific methodology—fall short of setting forth a reliable foundation for his

opinions.[4] In *Winebarger*, this Court found that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions." 2015 WL 1887222, at *10. *See also Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013) (finding that an expert's calculation of complications rates based on his personal experiences "has no basis in any reliable methodology"); *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 839 (S.D. W. Va. 2011) (an expert's opinions are inadmissible as "inconsistent with good science" if he makes "overreaching or speculative conclusions . . . based upon overreaching or speculative methodologies"). Here, Dr. Elliott seeks to offer broad opinions that are based on his personal experiences. Not only are these personal experiences uncorroborated by scientific studies, they are inconsistent with scientific studies. Accordingly, Dr. Elliott's opinions do not satisfy the rigors of *Daubert* scrutiny and should be excluded.

## III. The Court should preclude Dr. Elliott from offering design opinions, such as testifying that other synthetic mesh devices offer safer alternatives.

In his reports, Dr. Elliott criticizes the manner by which the devices at issue have been designed, such as by suggesting that devices with lighter weight, larger pore-sized mesh are preferable alternatives to TVT Devices. Ex. C, TVT Report at 18-23, 30-31, 38-39; Ex. F Prolift Report at 8, 32, 40-41, 54. The Court should preclude Dr. Elliott from offering such opinions at trial, because he is not qualified to offer them, he has not indicated with reasonable medical certainty that other mesh products are safer, and his opinions are unreliable.

### A. Dr. Elliott is not qualified.

There is nothing about Dr. Elliott's background, training, and experience as a urologist that would make him qualified to offer product design opinions. This Court has repeatedly found

[4] Dr. Elliott testified about a basic unfamiliarity with autologous sling literature and the experiences of other physicians, stating that "I can't speak to those. I can speak to my own experience." Ex. G, 9/26/15 Dep. 315:24-25; *see also id.* at 316:21-317:18.

that pelvic surgeons lack "the 'knowledge, skill, experience, training or education' as to product design that *Federal Rule of Evidence 702* requires" and that experience removing mesh devices and observing complications do not render them qualified to provide opinions concerning design. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561 (S.D. W. Va. 2014); *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015); *Cisson*, 948 F. Supp. 2d at 612-13. The Court should extend those rulings to Dr. Elliott in these cases.

**B. Dr. Elliott does not believe that there are safe synthetic mesh alternatives to TVT Devices.**

The Court may readily reject any suggestion by Dr. Elliott that the design of the TVT Devices may be improved in any respect, because he has definitively stated that he believes that all mid-urethral mesh slings are "unsafe." Ex. G, 9/26/15 Dep. 143:11-14, 144:16-18. According to Dr. Elliott, "[m]esh should not be placed in the vagina," period. *Id.* at 285:22.

Quite simply, Dr. Elliott should not be permitted to suggest that other mesh products offer a safer alternative given that he is unwilling to stand behind the alternative and confirm that it is safe and effective in treating SUI. In *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 712-13 (S.D. W. Va. 2014), another expert, Dr. Abhay Pandit, wished to offer vague, noncommittal testimony concerning how the mesh in TVT-O could be improved and suggesting that laser cut mesh was preferable. This Court precluded Dr. Pandit from offering these opinions because they were unreliable and because Dr. Pandit was unable to offer such opinions within a reasonable degree of medical certainty. *Id.* That same reasoning applies here. *See also American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 433 (Tex. 1997) (finding that plaintiffs did not prove that safer alternative designs were available because their experts testified that there was no cigarette design available that could have avoided lung cancer); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp.

2d 561, 573 (E.D. Pa. 2011) (observing that if there exists no FDA-approved alternative for the product, "there is no available alternative design of the drug for defendants to adopt").

**C. Lighter Weight/Larger Pore Size Mesh**

Dr. Elliott also should not be allowed to suggest that lighter weight, larger pore mesh is preferable, because his opinions are unreliable. Dr. Elliott has not conducted studies to compare the weight and pore size of the mesh in the devices at issue to the mesh in other commercially available devices. He has never treated a patient for SUI or POP with a lighter weight, larger pore mesh and cannot identify anyone else who ever has.

Without citing any source, Dr. Elliott claims that "[b]ased upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are low-weight, large-pore size, high porosity, monofilament, and capable of maintaining their elasticity under load will have the better results with fewer complications." Ex. C, TVT Report at 9-10. Although Dr. Elliott cites to certain studies elsewhere in his report, those studies pertain to hernia and prolapse mesh; those studies do not pertain to the intended use of TVT Devices—the surgical treatment of *SUI*. *Id.* at 14-18; Ex. G, 9/26/15 Dep. 166:1-167:24, 241:17-22, 323:12-324:4, 326:14-327:2. Therefore, these studies lend no support to his opinions with respect to the TVT Devices.

Dr. Elliott is unaware of any studies showing that lighter weight mesh is more efficacious than the mesh in TVT Devices. *Id.* at 238:5-239:16. When asked about complications, Dr. Elliott testified as follow:

> Q. Are you aware of any clinical studies showing a lower rate of complications in women who receive a lighter weight mesh for the intended use of treating stress urinary incontinence?

A. *No*. I've only seen it in pelvic organ prolapse data and in meshes. Meshes for hernia repairs, but it was not extrapolated, even though Ethicon knew about it, into stress urinary incontinence.

Q. All right. And you're not testifying that a lighter weight mesh would have worked better than the TVT mesh in the TVT retropubic application to treat stress urinary incontinence; are you?

MR. CARTMELL: Are you talking about efficacy only?

MR. SNELL: I can go with efficacy first.

A. There is no data out there on it. That would be an important thing to do before a launch is to study that to determine efficacy prior to widespread use.

Q. BY MR. SNELL: You would agree it's a benefit for the TVT retropubic device that they do have studies of 5 years, 10 years, or more duration in the literature?

MR. CARTMELL: Object to the form.

A. Yes, as we mentioned concerning efficacy, but not safety.

Q. BY MR. SNELL: Well, there's --

A. The lighter meshes, the larger pore, lighter weight meshes are for complications. Not for efficacy.

Q. And I understand you say that with regard to prolapse and hernia. My question to you is: With regard to complications, is it your opinion that a lighter weight mesh was used in the application of TVT for the treatment of stress incontinence, cut to 1.1 centimeters, that there would be a lower complication rate?

A. There's the *theoretical possibility of that*. However, *my ultimate opinion is no meshes should be placed transvaginally*.

*Id.* at 239:23-241:15 (emphasis added).

Similarly, when asked whether he could reliably state what complications are caused by the pore size of TVT, Dr. Elliott testified: "Specifically small pore, what role is that playing in percentage of the complications. No I cannot state that. . . . [W]e do know from the hernia mesh data and the Vypro mesh data that complications can be reduced with a large pore lightweight. It

has not been extended down into the TVT like it should have been. So you are correct. That data does not exist and it should exist." *Id.* at 273:2-25; *see also id.* at 274:14-275:9.[5]

A fundamental logical flaw and failure of proof behind Dr. Elliott's opinions about pore size and weight is demonstrated in federal judge Ron Clark's opinion in *Conklin v. Novartis Pharmas. Corp*, 2012 WL 4127295 (E.D. Texas 2012). Judge Clark in an MDL case found that an expert could not opine about an allegedly safer alternative design as required by Texas law because there was no evidence as to the alternative's utility. The court illustrated this by setting out the expert's premises and conclusions:

> **Premise:** Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause [bone disease]
>
> **Premise:** Other studies show that less Zometa will result in less [bone disease].
>
> **Conclusion:** A regimen using less Zometa will help treat cancer-related bone conditions.
>
> This is a classic logical fallacy—an irrelevant conclusion.

*Id.* at *9. The court found an impermissible "analytical gap," because there was no evidence that reducing the dosage would not only reduce the side effect but would "also be effective at fighting cancer-related diseases." *Id*. at *10. *See also In re AlloDerm Litigation*, Case Code 295, N.J. Superior Court of Middlesex County (Aug. 14, 2015), attached as Ex. F, at p. 22 (rejecting challenge to hernia repair product because plaintiffs failed to "prove with empirical evidence or reliable data that the alternative is actually safer and there was evidence it was safer at the time of manufacture").

Here, the same analytical gap exists. Dr. Elliott has suggested that the mesh in the devices at issue would have less inflammation if made of larger pore, lighter weight mesh. But

[5] Dr. Elliott also conceded that a lighter weight, larger pore Vypro mesh was found unsuitable even for treating prolapse. *Id.* at 285:3-287:25.

Dr. Elliott points to no studies, testing, or other scientific evidence whatsoever that these devices would have been equally effective as a treatment for SUI or POP if the mesh had those characteristics. Nor does Dr. Elliott point to any evidence that, had the mesh had such characteristics, there would not be an increased risk of other adverse events. Like the opinion stricken in *Conklin*, Dr. Elliott's opinions are supported by nothing more than the "naked conclusion" of the expert. That is not enough.

In *Huskey*, another expert, Dr. Abhay Pandit, wished to offer vague testimony concerning how the mesh in TVT-O could be improved and suggesting that laser cut mesh was preferable. 29 F. Supp. 3d at 712-13. This Court precluded Dr. Pandit from offering these opinions because they were unreliable and because Dr. Pandit was unable to offer such opinions within a reasonable degree of medical certainty. *Id.* That same reasoning applies here. As with *Huskey*, the Court should preclude Dr. Elliott from making vague suggestions that lighter weight, larger pore mesh, or any other synthetic mesh products are safer alternatives to the devices at issue, given Dr. Elliott's lack of qualifications and his own testimony discussed above.

**IV. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.**

For similar reasons, the Court should not allow Dr. Elliott to criticize mechanically-cut mesh or vise versa. Dr. Elliott criticizes TVT mesh that is cut mechanically, but then criticizes the alternative method to cut mesh with a laser. *See* Ex. C, TVT Report at 13, 23-27; Ex. E, TVT-Secur Report at 28-29. Because, as set forth above, Dr. Elliott has stated that no mid-urethral mesh slings should be placed in the vagina, Dr. Elliott should not be allowed to offer these criticisms. *See* Ex. G, 9/26/15 Dep. 143:11-14, 144:16-18, 285:22. Thus, even though Dr. Elliott's report states that "Ethicon continued to sell mechanically cut mesh for the TVT despite laser cut mesh being a safer option" (Ex. C, TVT Report at 26), he has explicitly testified

that he believes that laser-cut mesh is defective. Ex. G, 9/26/15 Dep. 224:22-25. According to Dr. Elliott: "They're both bad and both have their set of complications. So you're trading one set of problems for another set of problems." *Id.* at 226:21-24.

In any event, Dr. Elliott has not identified any reliable studies or medical literature that would support the suggestion that either approach is better than the other. He acknowledged that he is unaware of any clinical trial or other studies that have compared the two types of mesh, and he is unaware of any literature indicating that the complication rates for mechanically-cut mesh are any different than laser-cut mesh. *Id.* at 225:1-8, 226:12-15, 227:21-228:5. In fact, Dr. Elliott stated that "I don't think overall there's going to be a higher risk from one or the other," and that, notwithstanding what is set forth in his expert report, "I am not here today to say that laser cut is better or worse." *Id.* at 226:20-21, 228:16-18. *See Huskey*, 29 F. Supp. 3d at 712-13 (precluding non-committal testimony about laser cut mesh from Dr. Pandit).

Further, Dr. Elliott cannot play both sides of the fence and opine in a laser-cut mesh case that mechanically-cut mesh is preferable, and then turn around and opine in a mechanically-cut mesh case that laser-cut mesh is preferable.

The Court should also preclude Dr. Elliott from claiming that mechanically-cut TVT has "spiky" edges and causes "roping, curling, fraying, and particle loss." Ex. C, TVT Report at 25-26. Aside from the fact that he has conceded that he does not intend to testify that laser-cut mesh is preferable, Dr. Elliott has stated that he is unaware of any studies that "attribute clinical mesh exposure due to a sawing of the mesh." Ex. G, 9/26/15 Dep. 303:15-22. Dr. Elliott also stated that he is unaware of any medical literature that would support his opinions about fraying. *Id.* at 305:20-307:8.

## V. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

In his reports, Dr. Elliott criticizes Ethicon for allegedly failing to comply with certain duties owed by a medical device manufacturer. Dr. Elliott is not qualified to provide such testimony, and his opinions are unreliable.

### A. Research/Testing

Dr. Elliott faults Ethicon for allegedly not performing certain testing and conducting studies. *See, e.g.*, Ex. C, TVT Report at 29, 33-34, 37; Ex. F, Prolift Report at 13, 53, 55; Ex. G, 9/26/15 Dep. 240:17-19, 259:8-10, 271:9-16, 275:4-9, 303:21-23. The Court should exclude these opinions, which are of questionable relevance, because Dr. Elliott is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

As an initial matter, a lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) ("[A] product that is not defective and has not been tested at all remains free of a defect"). The "failure to test" claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were relevant, there is nothing in Dr. Elliott's background that would provide him with specialized knowledge about the testing that Defendants or other medical device manufacturers supposedly should have performed. He has never manufactured or even worked on the design of a medical device, much less had any involvement with FDA clearance of a medical device. Dr. Elliott's resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization

that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Dr. Elliott has no relevant experience, he is unable to identify a single rule or regulation that would require Defendants to conduct different testing. Moreover, Dr. Elliott does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal belief. In fact, when asked about how certain studies/testing should be conducted, Dr. Elliott responded that he did not know. *See, e.g.*, Ex. G, 9/26/15 Dep. Tr. 259:17-21 ("The basic unfortunate reality is it – I don't know if it could be done").

In *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 723 (S.D. W. Va. 2014), this Court precluded Dr. Jerry Blaivas from offering these same opinions, finding that "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." Further, the Court has determined that "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct." Ex. K, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014). *See also Hovey v. Cook, Inc.*, 2015 WL 1405565, at *11 (S.D. W. Va. Mar. 26, 2015) (noting in *Daubert* ruling that "plaintiff concedes that 'Dr. Elliott will not testify that defendant had an obligation to study and failed to do so'"). For these reasons, the Court should preclude Dr. Elliott from offering such testimony in these cases.

**B. Adverse Event Reporting**

Dr. Elliott also claims that Ethicon "fail[ed] to properly evaluate and act in response to adverse event reports." Ex. F, Prolift Report at 55. Dr. Elliott's experience as a urologist does

not qualify him to render opinions on adverse event collection and reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g.*, *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

**C. Training**

In his Prolift Report, Dr. Elliott also claims that Ethicon did not provide appropriate training to physicians. Ex. F, Prolift Report at 42-46. Dr. Elliott is not qualified to opine about the level of training that a manufacturer is required to provide, and he admitted that he was never participated in any Prolift training. Ex. L, Elliott Nov. 15, 2012 Dep. Tr. 113:3-8; Ex. M, Elliott Nov. 16, 2012 Dep. Tr. 387:11-21. Further, these opinions are irrelevant insofar as Dr. Elliott has not claimed that Plaintiffs' implanting physicians were inadequately trained. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances).

**D. Legal Conclusions**

Finally, certain of Dr. Shull's opinions entail legal conclusions. *See, e.g.*, Ex. F, Prolift Report at 4 (stating that "Ethicon failed to act as a reasonably prudent medical device manufacturer" and "breached its duty of reasonable care"). As this Court has held, testimony such as this that amounts to a legal conclusion is inadmissible. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 703.

## VI. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

Although he is not a biomaterials or polymer science expert (Ex. L, 11/15/12 Dep. 161:14-15; Ex. M, 11/16/12 Dep. 403:18-404:5), Dr. Elliott makes a number of assertions about biomaterials opinions that are unreliable, irrelevant, and/or otherwise improper.

### A. Degradation

Dr. Elliott claims that "[i]t is my opinion, to a reasonable degree of medical certainty, that polypropylene degrades in the human body causing the complications discussed throughout this report to women." Ex. C, TVT Report at 17. The Court should disallow such testimony, because Dr. Elliott cannot reliably state that any alleged degradation, even if true, causes clinical problems with women. Asked whether there are TVT studies correlating any particular complication with degradation, Dr. Elliott responded: "Well, no." Ex. G, 9/26/15 Dep. 249:2-6. Dr. Elliott further testified:

> Q. Are you aware of any reliable scientific studies that show the degree to which degradation causes any of these complications you just identified as compared to surgical technique, patient factors or any other causal elements?
>
> A. See, that's exactly what I've been trying to state this entire time. The whole device, as marketed, is bad because surgeons play a role. The patient may or may not. I think that's questionable. We talked about that already. I can't find an identifiable source there. But then you have a bad product put in.

*Id.* at 254:7-18. The Court should not allow Dr. Elliott to offer sheer speculation.

In *Bellew*, *supra*, the Court found that Dr. Elliott was competent to opine on mesh degradation because his report cited "numerous peer-reviewed studies and articles to support his assertions." Ex. K at 18. Unlike *Bellew*, the question here is whether Dr. Elliott can reliably connect alleged degradation to any clinical harm. He cannot do so, and therefore, these opinions should be excluded.

**B. Shrinkage/Contraction**

The Court should not allow Dr. Elliott to testify about shrinkage and contraction (Ex. C, TVT Report at 19), because his opinions are unreliable. The medical literature he cites in support of this opinion address hernia mesh, not SUI or POP mesh. *Id.* at n. 30-34; Ex. N-P. As Dr. Elliott acknowledges, hernia mesh is not cut and configured like TVT, hernia mesh does not have a sheath, and "TVT mesh has different forces placed upon it." Ex. G, 9/26/15 Dep. 193:20-194:4. During his deposition, Dr. Elliott cited to the Wang study, but that study makes no reference to contraction. *Id.* at 192:13-193:8; Ex. 19 thereto. Thus, Dr. Elliott's opinions are unreliable.

The Court should also preclude Dr. Elliott from testifying that TVT Device mesh shrinks or otherwise deforms "because there is no way to properly tension the TVT device." Ex. C, TVT Report at 30. Dr. Elliott is not qualified to testify about the ability to tension TVT Devices, because *he has never tried to do so* and admitted that "I can't tell you how to tension it correctly." Ex. G, 9/26/15 Dep. 43:3-8, 51:10-12, 315:18-19. His report does point to a single study that supports this opinion, and there is no gauge that assesses tension. *Id.* at 314:19-22.

**C. MSDS Sheet**

The Court should further preclude Dr. Elliott from suggesting that Ethicon's mesh should not be used in the vagina on the basis of the Prolene MSDS sheet, which suggests that it is incompatible with "strong oxidizers" such as chlorine and nitric acid. *See* Ex. C, TVT Report at 32-33. Dr. Elliott has no idea what is meant by "strong oxidizers." The MSDS does *not* forbid implantation in humans, and in fact, states: "No epidemiological studies or case reports suggest any chronic health hazards from long-term exposure to polypropylene decomposition products below the irritation level." Ex. Q. It thus provides no support for the opinions expressed.

Further, courts have found that an expert may not testify based on MSDS data sheets where the expert does not know how the statements in the MSDS were prepared. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (suggesting expert's ignorance of the tests utilized to formulate MSDS diminished reliability of MSDS); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (same); *Ingram v. Solkatronic Chem., Inc.*, No. 04-CV-0287, 2005 U.S. Dist. LEXIS 38304, *22-23 (N.D. Okla. Dec. 28, 2005) (citing *Turner* and *Moore* and excluding expert opinion under *Daubert* where expert opinion largely based on information in MSDS, but expert had no knowledge of how the MSDS was generated).

Dr. Elliott has offered no information at all on this topic that would be helpful to the jury, and this is an area far beyond his qualifications as a urogynecologist.

**D. Cytotoxicity**

According to Dr. Elliott, the Prolene mesh in TVT Devices has the "potential" for being cytotoxic. Ex. C, TVT Report at 28; *see also* Ex. G, 9/26/15 Dep. 270:17 (stating that cytotoxicity is only "possible"). The Court should prohibit Dr. Elliott from testifying about cytotoxicity, because Dr. Elliott may only speculate about whether any cytotoxicity—even if it exists—leads to any complications. When asked to identify any studies that show that cytotoxicity causes any TVT Device complications, Dr. Elliott responded "[t]here have been none . . . ." *Id.* at 266:8-11. Dr. Elliott further testified:

> Q. . . . So for the TVT retropubic device, are there complications which you believe are caused by cytotoxicity?
>
> A. *In theory, possibly* all of them, because cytotoxicity is cell death. Cell death will increase the foreign body response, the inflammatory response, subsequently increase the degradation, cracking, increase pain, increase the potential for infection. I'm saying possibly. It could be. . . . *That has not been studied to date*.

*Id.* at 267:4-15 (emphasis added).[6]

The only medical literature cited by Dr. Elliott in his reports about cytotoxicity is a study by Wang and others. Ex. C, TVT Report at 28-29; Ex. V. That study reported that only 2.4% of TVT patients encountered impaired wound healing/exposure, and 0.56% complained of dyspareunia. *Id.* at 1870. Dr. Elliott could not state how many of those patients developed those conditions as a consequence of cytotoxicity and stated only that "[t]hat would require a study by Ethicon to do that." Ex. G, 9/26/15 Dep. 267:16-272:12. According to Dr. Elliott: "How much of a role [this "possible" cytotoxicity] plays in all the other complications, *I don't know*. That needs to be studied . . . . I cannot attribute that to just cytotoxicity." *Id.* at 271:24-272:12 (emphasis added). Nor could Dr. Elliott explain why such a huge majority of TVT Device patients do not have complications if their TVT Devices are truly cytotoxic. *Id.* at 269:7-270:17.

**E. "Barbed-wire effect"**

In his Prolift report, Dr. Elliott claims that mesh degrades and "creates a '*barbed-wire*' effect." Ex. F, Prolift Report at 34. Dr. Elliott has no basis to make such an assertion in these cases. Dr. Elliott has testified that he cannot recall if he has ever seen Prolift mesh have such an effect, and he is unaware of any clinical studies that have reported such an effect. Ex. M, Elliott Nov. 16, 2012 Dep. Tr. 430:8-431:18. Accordingly, Dr. Elliott's opinion is unreliable, and use of the term is prejudicial and should be excluded.

## VII. The Court should exclude regulatory and marketing opinions.

In his Prolift report, Dr. Elliott makes a number of assertions about Ethicon's alleged interactions with the FDA and suggests that Ethicon did not comply with FDA regulations. *See, e.g.*, Ex. F, Prolift Report at 10, 12-13, 24, 38-39, 41, 44, 47. For instance, Dr. Elliott asserts that

[6] Ethicon reported its cytotoxicity data to the FDA, which determined that TVT Devices are safe and effective.

"Ethicon marketed and sold Prolift in the United States for more than three years without obtaining clearance by the FDA." *Id.* at 12. Quite simply, there is nothing about Dr. Elliott's background that would make him qualified to provide regulatory opinions. In fact, Dr. Elliott has conceded that he is "[b]y no means" an expert on regulatory matters and that he is unfamiliar with federal regulations governing medical devices. Ex. M, Elliott Nov. 16, 2012 Dep. Tr. 408:1-8, 410:15-17, 431:25-433:3. Moreover, Dr. Elliott would simply be providing a narrative summary of documents, and such evidence is otherwise irrelevant, prejudicial, and inadmissible.

In the same manner, Dr. Elliott should not be permitted to provide marketing opinions, such as making the highly inflammatory and improper assertion that "I agree with Ethicon's 2012 decision to cease marketing the Prolift System for use in the United States." Ex. F, Prolift Report at 3; *see also id.* at 13 (improperly speculating about the reason for Prolift's withdrawal from the market); *id.* at 12 (discussing Ethicon's alleged "marketing strategy"). As this Court has found, physicians such as Dr. Elliott have no competence to testify about product marketing, and their opinions are "not properly the subject of expert testimony." *Cisson*, 948 F. Supp. 2d at 614. Further, the opinions are speculative, irrelevant, and prejudicial.

**VIII. The Court should not allow other opinions beyond Dr. Elliott's expertise and/or that are otherwise improper.**

Dr. Elliott's report is replete with other statements that are beyond his expertise. Although he makes a number of statements about Ethicon's alleged knowledge and corporate conduct, (ie. claiming that Ethicon was motivated "for financial reasons" and that it engaged in a "disturbing pattern of ignoring . . . protocols"), and draws legal conclusions (ie. stating that "Ethicon failed to act like an appropriate manufacturer"), the Court has consistently found that such testimony is inadmissible. *See, e.g.*, Ex.C, TVT Report at 26, 36; Ex. F, Prolift Report at 4, 12, 47; *Cisson*, 948 F. Supp. 2d at 611; *Huskey*, 29 F. Supp. 3d at 703.

Similarly, Dr. Elliott has no special qualifications that would allow him to testify about bias. *See* Ex.C, TVT Report at 38. The Court should also not allow Dr. Elliott to testify about a medical condition that a Plaintiff's medical expert has not competently testified that the Plaintiff has sustained or likely will sustain. Ex. K, *Bellew* Order at 20 ("Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value").

Finally, the Court should similarly find that Ethicon may reserve for trial objections to Dr. Elliott's testimony that are based merely on a narrative summary of Ethicon documents. (*See, e.g.*, Ex. B, Expert Report at 40-52). *See, e.g., Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012) (excluding expert testimony based on defendant's corporate documents); *Hines*, 2011 WL 2680842, at *5 (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

**CONCLUSION**

For the foregoing reasons, the Court should limit Dr. Elliott's testimony in these cases.

Respectfully Submitted,

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327** |
| **THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*/s/ Christy D. Jones*

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